Complete Summary

GUIDELINE TITLE

Practice parameters for the prevention of venous thromboembolism.

BIBLIOGRAPHIC SOURCE(S)

Practice parameters for the prevention of venous thromboembolism. The Standards Task Force of the American Society of Colon and Rectal Surgeons. Dis Colon Rectum 2000 Aug;43(8):1037-47. [54 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Venous thromboembolism

GUIDELINE CATEGORY

Prevention
Risk Assessment

CLINICAL SPECIALTY

Colon and Rectal Surgery
Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To provide practice parameters for the prevention of venous thromboembolism

TARGET POPULATION

Patients undergoing surgery of the colon and rectum

INTERVENTIONS AND PRACTICES CONSIDERED

Physical Prophylactic Measures

1. Ambulation
2. Elastic stockings
3. Intermittent pneumatic compression boots

Pharmacologic Prophylactic Measures

1. Warfarin
2. Low-dose unfractionated heparin
3. Low-molecular-weight heparin
4. Heparin and regional anesthesia

Risk stratification

MAJOR OUTCOMES CONSIDERED

Rates of venous thromboembolism

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Risk

Risk Factors for Development of Postoperative Venous Thromboembolism

Not all risk factors carry equal weight. A history of prior venous thromboembolic disease is among the highest of risk factors for a new thromboembolic event, particularly if the previous event occurred in the recent past. Although most patients with this history will mention a typical inciting event, such as a coinciding operation, fracture, or a prolonged period of immobilization, some patients present with spontaneous thrombosis. Spontaneous cases are particularly worrisome, and these patients may harbor one of the genetic hematologic abnormalities leading to thrombosis. There are several well-described genetic hypercoagulate states that increase the risk of venous thromboembolism (see Table 1 below). The list is continually expanding. When "hereditary thrombophilia" is suspected in an elective situation, based either on the patient's personal or family history, a hematologic workup should be considered. These conditions pose

a very high risk for thromboembolism in a patient undergoing major abdominal surgery.

Table 1

Hereditary Hypercoagulable States
Activated protein C resistance
Factor V Leiden mutation
Antithrombin III deficiency
Protein C deficiency
Protein S deficiency
Dysfibrinogenemia
Antiphospholipid antibody syndromes Anticardiolipin antibodies
Lupus anticoagulant
Plasminogen disorders
Myeloproliferative disorders (e.g., polycythemia vera)
Prothrombin gene mutation 20210A
Hyperhomocystinemia

Risk of postoperative venous thromboembolism rises with increasing age. Age older than 40 years is usually listed as an independent risk factor, and the degree of risk increases exponentially with age, nearly doubling with each decade of life after age forty.

"Major abdominal surgery," "major general surgery," "complicated surgery," and "extensive pelvic dissections," are commonly cited as strong risk factors. Although the descriptors "major" and "extensive" are difficult to quantitate, they refer to the length of the procedure and the extent of tissue trauma. Authors have used minimal time intervals as short as 30 minutes and as long as two hours to define a "major procedure." Obviously any time limit is arbitrary, but probably all but the briefest of laparotomies will fall in this category of major abdominal surgery. In effect, major surgery can be regarded as a transient hypercoagulable state.

Malignancy increases the likelihood of venous thrombosis. However, the association between malignancy and venous thromboembolism is difficult to quantitate and "confounding factors such as age, extent of surgery, preoperative and postoperative management make it difficult to assess the real role of malignancy." Cancers are capable of expressing "procoagulant" substances, although this probably occurs in a minority of cases, as evidenced by the similarity of thrombosis in patients with and without cancer, and the rarity of Trousseau's syndrome. Widely disseminated metastatic disease and treatment with chemotherapy are more likely to produce these substances. But whatever the mechanism, malignancy often places patients at high to very high risk for venous thrombosis.

There are several other risk factors that may interact with the above major risk factors (see Table 2 below). These include inflammatory bowel disease, morbid obesity, prolonged immobility (greater than 72 hours), pregnancy, venous stasis, congestive heart failure, acute myocardial infarction, stroke (resulting in paralysis), and use of oral contraceptives.

Table 2

Risk Factors for Thromboembolism

Major abdominal or pelvic surgery
Age older than forty
Previous thromboembolic event
Hereditary hypercoagulable state
Malignancy
Morbid obesity
Inflammatory bowel disease
Stroke (with paralysis)
Prolonged immobilization
Heparin-induced thrombocytopenia
Congestive heart failure
Acute myocardial infarction
Oral contraceptives
Tamoxifen
Venous stasis

Users of oral contraceptives are at somewhat higher risk for the development of venous thromboembolism. At the very least, birth control pills seem to be an important risk cofactor. Recommendations for discontinuation of birth control pills before surgery are controversial, because the risk of discontinuation must be balanced against the risk of pregnancy, which itself is a risk factor for deep vein thrombosis. Females receiving postmenopausal hormonal replacement therapy are generally considered to be at little or no increased risk and need not discontinue these medications.

One group of patients taking exogenous hormones is at especially high risk. Factor V Leiden mutation, the predominant form of activated protein C resistance occurs in roughly 5 percent of females of European descent and in other ethnic groups as well. The use of oral contraceptive medication by females with this mutation puts them at risk for spontaneous thromboembolism and at very high risk for perioperative thromboembolism. Although routine screening for activated protein C resistance is not currently a standard of care, when recognized, these patients should avoid estrogen-containing compounds.

Tamoxifen, a selective estrogen modulator, is prescribed to females as adjuvant therapy for breast cancer. In addition, it now finds a role in patients with both precancerous lesions and in patients with strong family histories of breast cancer. Thromboembolism is a complication of tamoxifen therapy, which should be discontinued three weeks before elective major surgery.

Risk Stratification

Consensus reports on this topic make specific recommendations for venous thromboembolism prophylaxis based on the categories of low, moderate, or high risk. Recently a fourth category of very high risk or highest risk has been added and is becoming more widely accepted. A stratification scheme is necessary, because the more aggressive forms of prophylaxis have side effects and are more

expensive. These side effects cannot be justified unless there is an acceptable risk-to-benefit ratio for the patient. Although patients at low or very high risk are easily identified, the task of classifying the larger group of patients who fit somewhere in the middle can be somewhat arbitrary.

At the Fifth American College of Chest Physicians Consensus Conference on Antithrombotic Therapy (1998) presented a practical scheme for classification of risk levels for deep vein thrombosis. According to this scheme, "low risk" includes uncomplicated, minor surgery in patients younger than 40 years with no other risk factors. "Moderate risk" includes major surgery in patients older than forty with no other risk factors. "High risk" includes patients undergoing major surgery who are older than forty years with one or more additional risk factors. "Highest risk" includes major surgery in patients older than forty plus history of previous venous thromboembolism, malignancy, or hypercoagulable state.

This scheme is appealing because it is simple and is modeled after the traditional systems generated by previous consensus groups. This system does not account for every clinical situation. It favors a more aggressive approach to venous thromboembolism prophylaxis. For example, just by virtue of designating malignancy as a risk similar in importance to previous deep vein thrombosis, a large number of patients undergoing colon surgery become highest-risk patients.

Recommendations for Venous Thromboembolism Prophylaxis by Risk Classification (Table 3)

Each patient must be evaluated carefully, taking into account the risks of thrombosis vs. the risks of treatment. In higher-risk patients where the surgeon has justifiable concerns about the use of preoperative heparin, a case can be made for using intraoperative pneumatic compression boots and then using postoperative heparin if the serious risk of bleeding has passed.

Table 3

Thromboprophylaxis by Risk Classification*

	Low	Moderate	High	Highest
Example	Ambulatory surgery, no risk factors	Major abdominal symptoms, age > 40, no other risk factors	Major abdominal symptoms, age > 60, additional risk factors	Major abdominal symptoms, prior venous thromboembolism, malignancy, or hypercoagulable state
Calf vein thrombosis (without prophylaxis)	2%	10-20%	20-40%	40-80%
Clinical pulmonary embolism	0.2%	1-2%	2-4%	4-10%
Primary prophylaxis	None	Intermittent Pneumatic Compression	Low-dose Unfractionated Heparin	Low-dose Unfractionated Heparin (every 8 to 12

			(every 8 to 12 hours) or Low-molecular-weight Heparins	hours) or Low-molecular-weight Heparins
Alternate prophylaxis	None	Low-dose Unfractionated Heparin (every 12 hours) or Low-molecular-weight Heparins	Intermittent Pneumatic Compression +	Heparin and Intermittent Pneumatic Compression ++

+ Intermittent pneumatic compression boots offer prophylaxis where the risk of bleeding is high. Heparin may be started postoperatively after the risk of bleeding has passed.
++ Some data suggest that intermittent pneumatic compression combined with heparin may offer increased protection. Where the risk of bleeding is high, intermittent pneumatic compression may be used intraoperatively and heparin may be added postoperatively after the risk of bleeding has passed.

Low-Risk Patients

The typical low-risk patient is one undergoing minor surgery who has one or no risk factors. No specific measures are recommended for patients at low risk other than early ambulation. Unprotected, these patients have a 2 percent chance of calf vein thrombosis and a negligible risk of pulmonary embolus.

Moderate-Risk Patients

The typical moderate-risk patient is older than forty years of age, undergoing major abdominal surgery, with no other major risk factors. Moderate-risk patients can be treated with either intermittent pneumatic compression alone or low-dose unfractionated heparin. Moderate-risk patients have two risk factors. Unprotected, these patients have a 10 to 20 percent risk of calf vein thrombosis, and a 1 to 2 percent chance of a pulmonary embolism.

High-Risk Patients

High-risk patients have three or four risk factors. The typical high-risk patient is older than forty years of age, is having major abdominal surgery, and harbors additional risk factors. High-risk patients can be treated with low-dose unfractionated heparin (bid or tid) or low-molecular-weight heparins, although standard unfractionated heparin seems to be more cost-effective. If heparin cannot or should not be used, intermittent pneumatic compression should be substituted. When heparin has not been started preoperatively, the patient should be re-evaluated for postoperative heparin. Unprotected, these patients have a 20

to 40 percent risk of calf vein thrombosis and a 2 to 4 percent risk of pulmonary embolism.

Very-High-Risk Patients

A high-risk patient is upgraded to a highest risk category when certain additional risk factors are present. These include a prior history of thromboembolic events, hypercoagulable states, and possibly malignancy. Assuming no contraindication, highest-risk patients ideally should receive pharmacologic treatment such as low-dose unfractionated heparin (bid or tid) or low-molecular-weight heparins. Untreated, these patients have a 40 to 80 percent risk of calf vein thrombosis and a 4 to 10 percent risk of pulmonary embolism.

Intuitively, there may be some advantage to a strategy of dual methods, i.e. combining intermittent pneumatic compression with heparin. Several investigators have suggested this. This has been shown efficacious for patients undergoing cardiac and hip replacement surgery, but thus far there are no published data for colon and rectal surgery patients.

*Note: When surgeons anticipate an increased likelihood of unusual surgical bleeding, or when hematoma formation may seriously affect surgical outcome, surgeons may elect to withhold preoperative initiation of heparin prophylaxis, even from patients regarded as being at high or very high risk of developing venous thromboembolism. This strategy obviously involves a calculated risk, and for patients at high risk for venous thromboembolism, aggressive prophylaxis should be instituted as soon as possible after surgery.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Recommendations regarding venous thromboembolism prophylaxis, as a function of risk classification, are based on randomized trials. Unfortunately, most of the available studies that compare different forms of venous thromboembolism prophylaxis in a randomized, prospective manner study the larger group of general surgery patients, including those undergoing colon and rectal surgery, and other patient subsets. Therefore, these recommendations are extrapolated from multiple patient subsets.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

General benefits include:

- Decreased risk of deep vein thrombosis

- Decrease the additional potential morbidities of long-term anticoagulation, chronic venous insufficiency, pulmonary embolism, and possible fatality

Physical prophylactic measures

- Elastic stockings have been shown effective in reducing the incidence of venous clots, but only below the knees and only for patients at low risk.
- Intermittent pneumatic compression (IPC) boots have proven effective in reducing leg deep vein thrombosis in moderate-risk and high-risk surgical patients and compare favorably with low-dose heparin.

Pharmacologic prophylactic measures

- When administered in does adequate to prolong the prothrombin time to an international normalized ratio (INR) of 2 or 3, warfarin is highly effective in preventing deep vein thrombosis.
- Low-dose unfractionated heparin is an effective means of preventing both deep vein thrombosis and pulmonary embolism in general surgery patients.
- One of the benefits of low-molecular-weight heparin is the requirement for only one daily injection, which reduces patient discomfort and nursing care expense.

POTENTIAL HARMS

Pharmacologic Prophylactic Measures

- Low-dose unfractionated heparin can increase operative bleeding
- Heparin-induced thrombocytopenia and thrombosis (HIT) is a potential complication of heparin therapy.

Low-Molecular-Weight Heparin

- There is a risk of subarachnoid hemorrhage after regional anesthesia associated with low-molecular-weight heparin. The risk is further increased by concomitant use of antiplatelet agents, including nonsteroidal anti-inflammatory drugs or other anticoagulants, and traumatic epidural puncture.

CONTRAINDICATIONS

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Preoperative prophylaxis with warfarin at doses adequate to prolong the prothrombin time to an international normalized ratio (INR) of 2 or 3 is contraindicated in patients undergoing colon and rectal surgery because of inevitable bleeding during the surgery.

QUALIFYING STATEMENTS

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- It should be recognized that these guidelines should not be deemed inclusive of all proper methods of care or exclusive of methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding the propriety of any specific procedure must be made by the physician in light of all of the circumstances presented by the individual patient.
- No perfect system exists, and clinicians should avoid rigid, dogmatic interpretation of these or other guidelines.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Practice parameters for the prevention of venous thromboembolism. The Standards Task Force of the American Society of Colon and Rectal Surgeons. Dis Colon Rectum 2000 Aug;43(8):1037-47. [54 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 Aug

GUIDELINE DEVELOPER(S)

American Society of Colon and Rectal Surgeons - Medical Specialty Society

SOURCE(S) OF FUNDING

American Society of Colon and Rectal Surgeons

GUIDELINE COMMITTEE

Standards Task Force, American Society of Colon and Rectal Surgeons

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

An update is not in progress at this time.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Society of Colon and Rectal Surgeons (ASCRS) Web site.

Print copies: Available from the ASCRS, 85 W. Algonquin Road, Suite 550, Arlington Heights, Illinois 60005.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on February 13, 2001. The information was verified by the guideline developer on May 9, 2002.

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